

REMARKS/ARGUMENTS

Claims 1-11, 19, and 26-35 are pending. Claims 12-18 and 20-25 were previously cancelled. In the present amendment, Claim 1 has been amended to recite a donation ability of more than 60%. Support for this amendment is found in FIG. 1, which illustrates a donation ability of more than 60% in the claimed range of 1.5 to 7 wt% cellulose. Claim 34 has been amended to recite the amount of cellulose in the wound dressing, and recite that the control is a "gauze" dressing. In addition, Claim 27 has been amended to correct a typographical error.

A. Anticipation Rejection

On page 2 of the Office Action, the Examiner rejected Claim 19 under 35 U.S.C. § 102(b) as being anticipated by Ring et al., U.S. Patent No. 4,588,400. The Examiner relies upon column 5, lines 6-19 as teaching a cellulose obtained from a motionless medium, which is repeatedly washed in water to a ratio of about 1:90 cellulose to water. The Examiner further states that column 6, lines 1-4 teach reconstitution to 5% liquid content, and column 3, lines 49-51 teach cutting to the desired size. Applicant respectfully traverses the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). In this case, Claim 19 recites "a method for preparing a wound dressing comprising: statically producing a microbial cellulose pellicle using *Acetobacter xylinum*; isolating the pellicle with a cellulose to water ratio in the range of about 1:100 to about 1:500; drying the isolated pellicle to a cellulose content of 1.5% to 9 wt%; and forming a wound dressing by cutting the isolated pellicle." Applicant respectfully submits that the claimed invention is not anticipated for at least two reasons.

First, the Ring '400 Patent teaches a water-loaded cellulose pellicle comprising a cellulose to water ratio of 1:90.¹ Thus, because the claimed ratio of 1:100 to 1:500 falls outside this range, the claim is not anticipated.

Second, Applicant respectfully submits that Example 5, which is relied upon by the Examiner, does not teach or suggest the claimed invention. The cited passage states:

EXAMPLE 5

A water-loaded pellicle prepared according to Example 1 was allowed to air dry to form a thin, flexible sheet. The sheet was then immersed in glycerol whereupon it regained about 5% of its original liquid content. The resulting material was thin, strong and suitable for use as a wound covering.

Thus, the cited passage requires immersion with glycerol to regain about 5% of its original liquid content. The original liquid content was 3600 g/M² of water (Example 1, column 5, line 16). This corresponds to a liquid content of 5% x 3600 g/M² or 180 g/M². Thus, the resultant pad has a cellulose content of 40 g/M² (from Example 1, column 5 line 15)), and a liquid content of 180 g/M². This corresponds to a cellulose content of about 18 wt%, which is well outside the claimed range of 1.5 % to 9 wt %.

In light of the foregoing, Applicant respectfully request withdrawal of the anticipation rejection under 35 U.S.C. 102(b) with respect to Claim 19.

B. Enablement Rejections

1. Enablement Rejections of Claims 1-11, and 27-37

On page 2 of the Office Action, the Examiner rejected Claims 1-11 and 27-37 under 35 U.S.C. § 112, para 1. Relying on FIG. 1, the Examiner states that while the claims are enabled

¹ The Ring '400 Patent states: "The cellulose content of the saturated pellicle was determined to be about 40 g/M² and the water content about 3600 g/M²." This corresponds to a ratio of 1:90.

for a range of 1.5 to 4.5% microbial cellulose for the claimed 75% donation ability, the specification does not reasonably provide enablement for a range up to 9%.

In response thereto, Applicant has amended independent Claim 1 to recite a donation ability of 60% of its liquid weight. As the Examiner pointed out, FIG. 1 shows that at the claimed 7 wt% cellulose, the donation ability is greater than 60%.

Applicant respectfully submits that the Damien Declaration is commensurate with the scope of the claims. On page 12 of the Damien Declaration, the donative properties of the Examples in the Ring '400 Patent were 32% (glycerol and PEG), 11% (silver sulfadiazine), and 57% (petrolatum). Thus, the claimed donation properties are still outside those taught by the prior art. Thus, Applicant respectfully submits that the Examiner withdraw the anticipation rejection.

2. Enablement Rejections of Claim 34

On page 3 of the Office Action, the Examiner rejected Claim 34 under 35 U.S.C. § 112, para 1, as failing to comply with the enablement requirement. First, the Examiner states while Paragraph 0059 discloses a MCWD dressing used for the pain experiment in Paragraph 0069, the percent of microbial cellulose is not disclosed. Thus, the Examiner argues, that one of ordinary skill in the art has not been apprised of how to make the dressing.

Applicant respectfully submits that the MCWD dressing used in the clinical trials was the XCELL® dressing described in Paragraph 0050, containing about 4.3% cellulose. Applicant respectfully submits that one skilled in the art, when viewing the specification as a whole, would readily understand that the product tested and described in Examples 4 and 5 was the commercial XCELL® product referenced in the application. Thus, Applicant respectfully submits that the

specification as a whole teaches one skilled in the art how to make a suitable dressing to achieve the claimed reduction in pain. Withdrawal of the rejection is respectfully submitted.

Second, on page 3, the Examiner also rejected Claim 34, stating that because the specification, "while being enabling for a non-adhesive gauze dressing, does not reasonably provide enablement for any type of gauze dressing." The Examiner further states that "[i]n paragraph 60, applicants disclose a gauze dressing as their control" and "[n]o other is specified." Applicant has carefully reviewed the enablement rejection, and it is not entirely clear to Applicant what the rejection pertains to. Presumably, the Examiner has requested that the control be recited as a "non-adhesive gauze dressing," similar to Claims 27, 28, 29, and 31 (which were not rejected). Applicant thus has amended Claim 34 accordingly. Support for the amendment is found in Paragraph 0059 and FIG. 4 of the patent application. Withdrawal of the rejection is respectfully requested.

C. Indefiniteness

On page 3 of the Office Action, the Examiner rejected Claims 30, 31, and 34 under 35 U.S.C. § 112, para 2 as being indefinite. The Examiner indicated that it was unclear as to when the claimed pain occurs. The Examiner inquires as to whether the pain occurs during the time the dressing is in place or upon removal.

MPEP 2173.02 emphasizes that the definiteness of claim language must be analyzed, not in a vacuum, but in light of the content of the particular application disclosure. In this case, Applicant respectfully submits that the pain could occur at either time, if reported by the patient as such. As set forth in the specification, the pain scale was comprised of a 4-point rating scale from "none" to "severe." Thus, the patient could have reported the associated pain during either

event. As such, Applicant respectfully submits that the claim is not indefinite when read in light of the specification. Withdrawal of the rejection is respectfully requested.

D. Claim Informalities.

On page 4 of the Office Action, the Examiner objected to Claim 27. In response thereto, Applicant has corrected the typographical error. Withdrawal of the objection is respectfully requested.

E. Objections to the Disclosure

On page 4 of the Office Action, the Examiner objected to the disclosure. In response, Applicant has corrected the typographical error in Paragraph 0014, and has added a description of the squares to FIG. 1. Withdrawal of the objections is respectfully requested.

In view of the foregoing amendments and remarks, it is respectfully submitted that the claims are now in condition for allowance and eventual issuance. Such action is respectfully requested. Should the Examiner have any further questions or comments which need be addressed in order to obtain allowance, please contact the undersigned attorney at the number listed below.

Acknowledgement of receipt is respectfully requested.

Respectfully submitted,

By: 

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